GREAT SHIPS INITIATIVE (GSI)
QUALITY MANAGEMENT PLAN (QMP)

2010

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1. INTRODUCTION

This Quality Management Plan (QMP) details the structure of the Great Ships Initiative's (GSI's) quality system from an organizational perspective. The plan covers all aspects of GSI's commitment to quality including policies and procedures; criteria for and areas of application; roles, responsibilities, and authorities; and assessment and response. It is the framework for planning, implementing, documenting, assessing and reporting the GSI's quality assurance and quality control (QAQC) activities.

2. BACKGROUND

The Great Ships Initiative (GSI) is a regional effort devoted to ending the problem of ship-mediated invasive species in the Great Lakes-St. Lawrence Seaway System and globally. In support of that goal, the GSI has established superlative freshwater ballast treatment evaluation capabilities at three scales—bench, land-based, and on board ship.

The GSI awards its independent status-testing services to developers of ballast treatment systems and processes determined to be promising. GSI status-testing is performed at the scale appropriate to the state of development of the target treatment system, with the goal of facilitating the rapid progression of meritorious ballast treatment systems through the research and development and approval processes to a market-ready condition.

GSI has no involvement, intellectual or financial, in the mechanics, design or market success of the actual treatment systems it tests. To ensure that GSI tests are uncompromised by any real or perceived individual or team bias relative to test outcomes, GSI test activities are subject to rigorous QAQC procedures and documentation. As described in this document, GSI also subjects itself to rigorous quality management policies and procedures. This attention to QAQC assures high quality and credible evaluation of GSI and its findings.

3. GSI QUALITY SYSTEM MANAGEMENT AND ORGANIZATION

3.1. Policy

The GSI's quality management policy is guided by four operating principles:

1. *Credibility* – GSI's quality system assures high quality and credible evaluation of GSI projects and project findings.

2. *Support* – GSI quality management personnel support the GSI PI and members of the GSI research team by providing them with the quality tools and resources they need to effectively implement GSI projects and activities.

3. *Flexibility* – GSI's quality system is flexible in that it can be easily altered to respond to new or different information.

4. *Improvement* – GSI works continuously to improve its quality system through identification, evaluation and resolution of problem areas and potential issues of concern.

3.2. Goals and Objectives

The overarching goal of GSI is to resolve the problem of ship-mediated invasive species in the Great Lakes as quickly, effectively and economically as possible, and in coordination and cooperation with prevailing regulatory regimes. The specific objective of GSI is to accelerate research, development and implementation of effective ballast treatment systems for ships that visit the Great Lakes from aboard. The GSI's quality system works to support these goals and objectives by ensuring that GSI implements projects and activities that are based on sound science and provide information of high quality. The GSI's quality system also works to ensure that GSI projects and activities are uncompromised by any real or perceived individual or team bias relative to test outcomes, and that they are of the highest credibility.

3.3. Allocation of Appropriate Resources

GSI is committed to allocating adequate resources to meet the goals and requirements of its quality system. GSI currently authorizes three members of its personnel to work on quality system activities—a Senior Quality Systems Officer, a Senior QAQC Officer, and an Assistant QAQC Officer. The three work in partnership to implement and assess the GSI quality system. They are involved in the daily activities of both GSI management and research team personnel. They are also provided with the necessary tools and resources to successfully undertake their respective roles. These include access to training programs, conferences and workshops, as well as reference and guidance documents.

3.4. Organization

The GSI is a project of the Northeast-Midwest Institute (NEMWI)—a Washington, D.C-based private, non-profit, and non-partisan research organization dedicated to the economic vitality, environmental quality, and regional equity of Northeast and Midwest states. The project is carried out collaboratively with contracting entities including the University of Wisconsin-Superior (UW-S), AMI Consulting Engineers, Broadreach Services, and the University of Minnesota-Duluth (UM-D). For purposes of this QMP, GSI is defined as the testing organization.

3.4.1. Principal Investigator and Project Manager

Ms. Allegra Cangelosi of NEMWI is the GSI Principal Investigator and Project Manager (GSI PI). She is also responsible for planning and leading the overall GSI research agenda at the bench, land-based and ship board scales; developing experimental designs; approving quality

system documents and standard operating procedures (SOPs); and making all final decisions on GSI land-based facility engineering and operational modifications and upgrades. In coordination with other GSI research team personnel, she is responsible for analyzing GSI experimental outcomes and writing up findings. She is also responsible for lining up the GSI research activities each year and funding to support them, and interaction with the project Advisory Committee, regulatory community and public. She is assisted by Ms. Nicole Mays of the NEMWI in many of these capacities.

3.4.2. Advisory Committee

A GSI Advisory Committee comprises top-level officials of key stakeholder groups, and provides direct input to Ms. Cangelosi, advising GSI award decisions, program direction, finances and fund-raising. The GSI Advisory Committee, which meets 3-4 times a year, includes elected leadership, environmental organizations, port directors and federal officials from the United States and Canada, and industry representatives.

3.4.3. Industry Outreach

The American Great Lakes Ports Association advises the project, assuring that the GSI is meeting the needs of the maritime industry; and coordinating maritime industry and supply chain outreach.

3.4.4. Technical Advisors

GSI draws on advice from many technical advisors. It also calls upon these advisors to review applications for GSI services from time to time. The relationship with these advisors is informal, voluntary, and on an as-needed basis. Experts include marine engineers, process engineers, toxicologists, biologists and test facility operators.

3.4.5. Financial Management

Ms. Amy Brooks, an independent consultant from Broadreach Services, is the GSI Financial Manager. In this role she is responsible for management of all GSI accounts and financial documents. She also works closely with the GSI PI to develop budget projections, planning documents, and financial information for grant applications.

3.4.6. Quality Management Personnel

Ms. Nicole Mays of NEMWI is the GSI's Senior Quality Systems Officer responsible for development and maintenance of this QMP, the GSI's Quality Assurance Project Plans (QAPPs) and SOPs, and writing of QAQC annual reports. Ms. Kelsey Prihoda of the UW-S's Lake Superior Research Institute (LSRI) is the GSI's Senior QAQC Officer. She and a GSI Assistant QAQC Officer are responsible for implementing all GSI project-specific QAQC activities including audits and assessments, and write-up of QAQC reports on specific test activities. Ms.

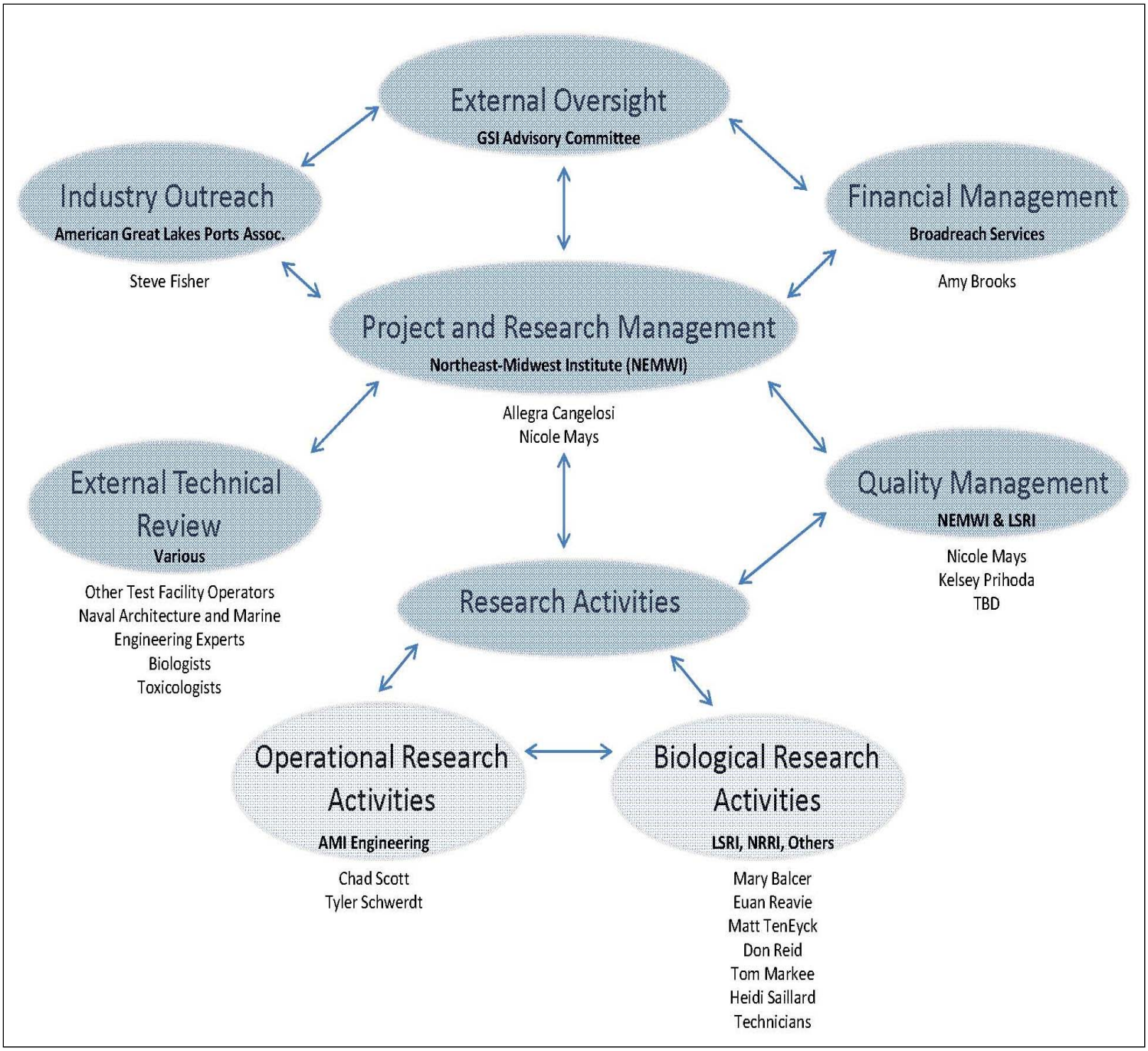
Prihoda is also responsible for assisting in the development of SOPs and project-specific QAPPs, and facilitating real-time communication between the research team and Ms. Cangelosi during all test activities.

3.4.7. Research Team Members

Researchers from LSRI and the UM-D's Natural Resources Research Institute (NRRI), among others, provide critical scientific and technical expertise and implementation services to the GSI PI. Dr. Mary Balcer of the LSRI is the project's lead zooplankton ecologist. She is also the team leader for the UWS-LSRI staff engaged in GSI research activities. Dr. Euan Reavie of the NRRI leads all phytoplankton analysis and NRRI staff. Mr. Matthew TenEyck of LSRI leads all bench-testing and Whole Effluent Toxicity (WET) tests. Mr. Tyler Schwerdt of AMI Consulting Engineers provides engineering expertise and services in support of GSI testing activities.

Figure 1 details the GSI's organizational structure.

Figure 1. Organizational Structure of the GSI.



3.5. Projects and Activities

GSI's current suite of projects and activities includes independent third party ballast treatment evaluations at three scales—bench, land-based, and shipboard. Each scale is dedicated to addressing specific evaluation objectives. These include:

GSI Bench-Scale Tests

- Range finding for effective doses under a range of ambient conditions;
- Chemical degradation over time under a range of ambient conditions;
- Detection of any residual toxicity under a range of ambient conditions; and
- Confirmation of treatment process.

GSI Land-Based Tests

- Detection of scale-up, mechanical operation issues;
- Effectiveness of a dose with respect to the full range of ambient organisms; and
- Detection of any whole effluent toxicity.

GSI Shipboard Tests

- Confirmation of biological and operational performance as expected in the ship environment; and
- Confirmation of performance as expected under a broad range of ambient conditions.

GSI status testing is performed at the scale appropriate to the treatment state of development, with the goal of helping meritorious ballast treatment systems to progress as rapidly as possible to an approval-ready and market-ready condition. Developers of ballast water treatment systems apply for GSI research services online, and awards are offered based on an objective external review process, regardless of the state of development of the proposed treatment. U.S. Environmental Protection Agency Environmental Testing Verification (ETV) testing is performed consistent with ETV protocols, and type-approval testing is conducted consistent with relevant regulatory requirements.

To assure relevancy of test output, GSI test protocols, generally, are as consistent with the International Maritime Organization (IMO) Convention and federal and state requirements as practicable. GSI tests are also third party assessments. They are completely independent of any vested interest in outcomes. Tests are supported by general project funds which derive from federal and state agency grants, Great Lakes port contributions, and in-kind contributions by the local government and universities. None of these funds come to the GSI with any strings other than timely public disclosure of methods and findings.

3.6. Authority

In order to meet its quality system goals and objectives, the following section outlines the specific roles and responsibilities of GSI personnel with respect to the GSI quality system.

GSI Principal Investigator and Project Manager

- Leads GSI research team;
- Approves GSI budget and planning processes, including allocation of adequate resources to GSI's quality system and for personnel training;
- Designs and implements the overall GSI research agenda;
- Approves GSI quality system documents (i.e., QMP, QAPPs, SOPs);
- Issues stop/go orders on day-to-day test activities;
- Issues stop/go orders on any SOP deviations deemed necessary during testing;
- Ensures GSI addresses quality management in all project and activity areas, and that appropriate documentation is developed;
- Ensures GSI complies with this QMP and other quality system documents;
- Maintains an active line of communication with GSI quality management personnel;
- Requires and facilitates implementation of corrective actions and recommendations for improvement; and
- Fosters an atmosphere where quality management practices are a beneficial, integral and requisite part of GSI daily activities.

GSI Quality Management Personnel

- Develop GSI QMPs, QAPPs, and other quality system documents for GSI PI approval;
- Develop and review SOPs for GSI PI approval;
- Facilitate GSI compliance on a day-to-day basis with this QMP, GSI QAPPs and other quality system documents during all test activities;
- Schedule and implement quality system audits and assessments;
- Generate and report results of audit and assessments;
- Monitor and report GSI quality system progress;
- Make recommendations to the GSI PI for GSI quality system improvements.
- Maintain adequate independence and separation from GSI personnel involved in data collection and analysis to assure objective review.

GSI Senior Research Team Personnel

- Support the GSI PI in developing research agenda, and experimental designs;
- Develop relevant methods for inclusion in SOPs;
- Directly implement test activities consistent with GSI quality system documents;
- Help select, schedule and supervise GSI research team members to assure their work is consistent with quality system documents;

- Support development of GSI quality system documents (i.e., QMP, QAPPs, SOPs);
- Ensure GSI addresses and correctly implements quality management in all project areas and that appropriate documentation is developed;
- Maintain active lines of communication with GSI quality management personnel; and
- Implement corrective actions required by the GSI PI in response to GSI QAQC assessments.

GSI Research Team Personnel

- Support senior research team personnel;
- Implement test activities consistent with GSI QAPPs and SOPs;
- Maintain active lines of communication with GSI quality management personnel;
- Respond and report to senior research staff and implement corrective actions that may be required.

4. GSI QUALITY SYSTEM COMPONENTS

GSI uses a wide variety of quality management tools to implement its quality system. These include quality system documentation, project-specific documentation, routine procedures documentation, project-specific audits and assessments, and training and certification.

4.1. Quality System Documentation

4.1.1. Quality Management Plan (QMP)

This document details the structure of the GSI's quality system from an organizational perspective. It covers all aspects of GSI's commitment to quality including policies and procedures; criteria for and areas of application; roles, responsibilities, and authorities; and assessment and response. It is the framework for planning, implementing, documenting, and assessing the GSI's quality assurance and quality control (QAQC) activities.

The GSI Senior Quality Systems Officer is responsible for preparing the QMP, with the document based on the U.S. EPA's "*EPA Requirements for Quality Management Plans*" to the greatest extent possible. The QMP is distributed to the GSI PI for review in draft form. Once a draft is finalized, the document is approved and forwarded to GSI senior research personnel and QAQC officers. Draft and final copies of the document are posted to the GSI SharePoint intranet website; the final version may also be posted to the GSI public website. The GSI's QMP is valid for a maximum period of five years, with an annual review and revision (as needed) occurring at the end of each calendar year.

4.1.2. Quality System Annual Report

The GSI Quality System Annual Report documents the GSI's quality system activities over the previous calendar year, including a summary of the year's projects and activities; a summary of the year's project-specific audits, assessments and responses; a list of quality system documentation and SOPs developed during the year; a list of quality management training GSI personnel received during the year; a discussion on the status of the GSI quality system including strengths, weaknesses, successes and problems, and recommendations for improvements; and an assessment of the adequacy of the GSI QMP and recommended changes. The GSI Senior Quality Systems Officer is responsible for preparing the report in conjunction with the GSI Senior QAQC Officer. Once a draft is finalized, the document is then passed on to the GSI PI for approval. The final report is distributed to relevant GSI research team personnel. Final copies are also posted to the GSI SharePoint intranet website.

4.2. Project-Specific Quality Documentation

4.2.1. Quality Assurance Project Plans (QAPPs)

GSI's Quality Assurance Project Plans (QAPP) describes the activities undertaken by GSI to assure the quality and credibility of its project-specific research findings, i.e., at the land-based facility or bench-scale of testing. Each QAPP covers all aspects of quality assurance/quality control (QAQC) relative to the specific project area, including data quality indicators, evaluation processes, performance measures and acceptance criteria; instrument certification and calibration; personnel training requirements; documents and records; data management; and QAQC assessments and response actions.

The GSI Senior Quality Systems Officer, in conjunction with the GSI Senior QAQC Officer, is responsible for developing the QAPPs. The plans follow the format of the U.S. Environmental Protection Agency's (EPA's) "*EPA Guidance for Quality Assurance Plans*" to the greatest extent possible. Draft QAPPs are distributed to relevant GSI senior research personnel for review and comment. Once a draft is finalized, the documents are then passed on to the GSI PI for review and approval. Draft and final copies of QAPPs are posted to the GSI SharePoint intranet website; the final versions may also be posted to the GSI public website. All QAPPs, once approved, are valid for a period of five years, though they are reviewed annually and revised as needed.

To date, the GSI has developed two QAPPs: *GSI/QAQC/QAPP/LB/1 - Quality Assurance Project Plan for Great Ships Initiative (GSI) Land-Based Tests (2010)*, and *GSI/QAQC/QAPP/BS/1 - Quality Assurance Project Plan for Great Ships Initiative (GSI) Bench-Scale Tests (2010).*

4.2.2. Field and Laboratory Notebooks

Bound field and laboratory notebooks, each having a unique identification code, are used to record observations, sampling details, and laboratory and field measurements. Notebooks are

also used to record instrument and equipment calibration and maintenance information. GSI personnel are responsible for maintaining the notebooks on site, creating electronic copies, and posting to the GSI SharePoint website for storage and archiving.

4.2.3. Forms and Records

Specific forms are used to record sample collection and analysis data. All relevant GSI senior research personnel are responsible for ensuring that the forms are correctly filled out. They are also responsible for maintaining the forms on file, creating electronic copies, and posting to the GSI SharePoint website for storage and archiving. In general, hard copies of all forms are stored in three-ring binders, each with a unique identification code.

Specific forms are also used to record sample custody, handling and storage information. Chain of custody forms are employed only when an outside laboratory is contracted to conduct sample analyses. All relevant GSI senior research personnel are responsible for ensuring that the forms are correctly filled out at the time of changes to sample custody, and sample handling and storage. They are also responsible for maintaining the forms on file, creating electronic copies, and posting to the GSI SharePoint website for storage.

In addition, specific forms are used to record operation, maintenance and safety information. The GSI Land-Based RDTE Facility Operations Manager is responsible for ensuring that all forms associated with safety (i.e., confined space entry permit forms, daily safety checklist) and operation and maintenance of the land-based test facility are correctly filled out. It is the responsibility of the GSI Land-Based RDTE Facility Operations Manager to ensure that equipment maintenance and instrument calibration is properly documented, and that forms are maintained on file, and also posted to the GSI SharePoint website for storage.

4.3. Routine Procedures Documentation

4.3.1. Standard Operating Procedures (SOPs)

SOPs are used to implement all GSI test activities. This facilitates consistent conformance to technical and quality system requirements and increases data quality. The SOPs include both programmatic and technical processes and procedures such as organism culturing; operation of the GSI Land-Based RDTE facility; sample collection, labeling, analysis and custody; and safety.

GSI SOPs are developed by the relevant GSI senior research personnel in conjunction with the GSI Senior Quality Systems Officer and GSI Senior QAQC Officer. The GSI Senior Quality Systems Officer is responsible for distributing finalized SOPs to the GSI PI for approval. Draft and final copies of all SOPs are posted to the GSI SharePoint website; the final versions are also posted to the GSI public website. All GSI SOPs are updated on an as-needed basis.

To date approximately 50 SOPs have been finalized, with many more in draft form or planned.

The SOPs follow a common format and include specific QAQC procedures and metrics. GSI SOPs are grounded in published standard methods. They are also consistent with international and domestic guidelines where they exist. All GSI SOPs are subject to periodic review and revision to assure that the most up to date approaches are employed

4.4. Project-Specific Audits and Assessments

GSI assesses its quality system on a project by project (i.e., test by test) basis using a variety of tools. In this situation, one project/test is defined as a series of trials of a specific ballast treatment system. For example, one test may constitute a set of five trials of a ballast treatment system at the GSI land-based facility. The purpose, procedural details, and implementation frequency of each of these assessment tools are outlined below.

4.4.1. Project-Specific Audits

GSI QAQC Officers assess the implementation of project-specific QAPPs and SOPs during each test of a ballast treatment system. At the end of the test duration, the officers provide reports to the GSI Senior Quality Systems Officer and GSI PI. The reports include a table listing deviations to the specific QAPP associated with the testing and a table listing deviations to the specific SOPs that were used during the testing. GSI QAQC Officers also verify data recording and archiving procedures by randomly evaluating data recording forms and field notebooks for completion, compliance and correct storage procedures.

4.4.2. Project-Specific Assessments

Following completion and verification of a data set associated with a specific ballast treatment test, GSI QAQC Officers determine if the data quality objectives outlined in the relevant GSI QAPP have been successfully met. GSI QAQC Officers also determine if the performance criteria outlined in the relevant GSI QAPP have been successfully met. Results are provided in reports submitted to the GSI Senior Quality Systems Officer and GSI PI; final copies are stored on GSI SharePoint.

4.5. Training and Certification

Attendance at training courses is recorded by GSI Quality Management Personnel. GSI Quality Personnel maintain records of the quality system training in a specific folder on GSI SharePoint. A summary of the quality system training is also provided in the annual report, including, but not limited to, a list of the courses offered and the number of attendees.

In addition, GSI quality management personnel are responsible for maintaining on the SharePoint intranet website copies of all training records. Documents are saved to individual personnel folders in the QAQC section of the website. Resumes are also posted to these folders, and quality management personnel are responsible for ensuring the resumes are up-to-date.

5. PERSONNEL QUALIFICATIONS AND TRAINING

GSI is committed to providing adequate training to its personnel. GSI is also committed to ensuring that personnel have the necessary education, qualifications, and experience needed to develop and control data quality. The following sections describe the GSI's quality system and project-specific training program.

5.1. Quality Systems Personnel Training

GSI quality systems personnel regularly attend national conferences, meetings and workshops on quality management and the development of quality management materials and protocols. Quality personnel also participate in training courses and webinars on quality management topics, such as data quality assessment and QAPP development. This assures that GSI quality personnel receive up-to-date training on a variety of quality assurance subjects.

5.2. Quality Management Training for Research Personnel

GSI research personnel receive training every two years on the GSI quality system or whenever a new QMP is developed and/or significant revisions made to an existing QMP. All new personnel receive initial quality system training within one month of joining the GSI. As part of this exercise, personnel are given an overview of the contents of this QMP and the location, on the GSI SharePoint intranet site, of the current QMP. Personnel are also encouraged to use the QMP as a reference in support of project-specific QAQC activities. Quality system training is provided by the GSI Senior Quality Systems Officer. The GSI Senior Quality Systems Officer is also responsible for maintaining records of those personnel that have received training. This information is housed in a specific subfolder of the GSI QAQC section of SharePoint.

5.3. Project-Specific QAQC Training for Research Personnel

Project-specific QAQC training is provided at least every two years to all relevant GSI personnel. Generally this training is conducted prior to the start of research activities. Training may consist of seminars or classes, or on-the-job training. For example, those GSI personnel involved in land-based research activities at the GSI facility in Superior, Wisconsin receive training on the GSI land-based QAPP prior to the start of testing in May/June. Training generally involves (1) an overview of GSI's Quality System; (2) specifics on GSI project-specific QAPPs; and (3) Data verification and validation; and (4) technical assessments and auditing.

5.4. Personnel Qualifications

Those GSI senior research personnel who supervise technicians are responsible for ensuring that staff have the required experience and/or qualifications to do their jobs, including those related to the GSI quality system. Senior personnel are responsible for discussing quality training needs with personnel during annual performance evaluations. As part of personnel performance

evaluations, senior personnel are encouraged to incorporate training and refreshment training courses into the individual's development plan to maintain competencies.

5.5. Quality Management Library

GSI quality management personnel are responsible for developing a library of pertinent quality management documentation to be used in quality system training exercises. Library materials include PowerPoint presentations, and one-page summaries describing the GSI quality system and its specific components.

6. PROCUREMENT OF ITEMS AND SERVICES

GSI is committed to ensuring that procured items and services are delivered in a timely fashion, and are within GSI specifications. The following sections describe GSI's procurement procedures.

It is the GSI policy that quality system requirements be explicitly addressed when acquiring items or services. This policy applies to procurements such as contracts and purchasing orders for items, as well as to cooperative agreements and participation agreements for services.

6.1. Procurement of Items

Since GSI operates as a "virtual" organization, it utilizes the services of its managing and contracting entities for its procurement needs. For example, NEMWI is responsible for procuring items on behalf of the GSI PI, UW-S is responsible for procuring items on behalf of LSRI personnel involved with GSI, and AMI Engineering is responsible for procuring items related to operation of the Land-Based RDTE Facility.

In general, the procurement of items for GSI research activities is based on a review of several criteria that will ultimately lead to a decision that constitutes the best value to the contract. The GSI PI in conjunction with senior personnel is responsible for carrying out the review and ultimately awarding the final contract. Review criteria include:

- Meets technical requirements;
- Cost of product;
- Availability of product;
- Past performance and experience providing similar products;
- Demonstrated ability to meet the intended quality requirements;
- Detailed work plans, including subcontractors, etc.

All requests must be approved by the GSI PI prior to purchase. The GSI Financial Manager issues purchase orders linked to funding sources, which assures that funding for the order is available.

In addition, the GSI PI and/or senior personnel are responsible for ensuring that quality requirements are embedded in procurement documents and that these requirements can be met by contractors. In turn, AMI, a private engineering consulting firm located in Duluth, Minnesota, serves as the owner's representative, and has been engaged to establish specifications and recommend sourcing of equipment and related services. As owner's representative, AMI is responsible for ensuring that approved suppliers provide acceptable items and services. This includes inspection of products received to ensure that content are consistent with anticipated quality, and also evaluation of items against procurement documents to ensure that specifications are met. If products consistently fail to meet quality standards, the GSI PI and/or senior research personnel have the authority to take remedial/punitive steps that may include, but are not limited to, nonpayment to suppliers and selection of alternative vendors or suppliers.

6.2. Procurement of Services

GSI uses four mechanisms to procure services. The first mechanism is the creation and maintenance of co-operative agreements to establish clear relationships between GSI and federal agencies, e.g.., the Maritime Administration. The second mechanism involves the creation and maintenance of grant agreements to establish relationships between GSI and funding organizations, including federal agencies. The third mechanism is the creation and maintenance of memoranda of understanding to establish relationships between the GSI managing entity (NEMWI) and contracting entities, e.g., UW-S; the AMI Consulting Engineers, and NRRI. Finally, the fourth mechanism involves the use of participation agreements to establish relationships between NEMWI and ballast treatment developers that would like to receive GSI services in the form of bench or land-based testing. In this situation, non-disclosure agreements may also be drafted between the parties.

GSI contracts and agreements detail quality objectives and quality metrics to assure quality service. This is the first step in the process of ensuring that services produce results or products of acceptable quality. Good communication between parties is also crucial to a mutual understanding of expectations and how quality will be defined. Methods used to determine quality (i.e., progress and final reports) are established prior to project implementation so that both parties understand how quality will be assessed.

6.3. Procurement Documents

It is the responsibility of the GSI Financial Manager to save copies of all procurement documents to the appropriate subfolder on the GSI SharePoint intranet site. This includes original and revised documents. Documents must also be signed (either electronically or by hand) by the GSI PI before they are finalized and saved to SharePoint. Packing slips or other evidence of receipt of goods is maintained and recorded on SharePoint by AMI personnel. Product documentation including warranties and owners manuals are also filed and maintained by AMI.

6.4. Changes to Procurement Documents

All significant changes to procurement documents require review and approval by the GSI PI. All parties initiating approved procurement activities are required to document changes made to the original procurement and the reason for the change. Similar quality assurance procedures ensuring the quality of the revised procurements are also required to certify that received items reflect the revised specifications and performance standards.

7. DOCUMENTS AND RECORDS

GSI has established and maintains procedures for the timely development, review, approval, dissemination, format, and maintenance of documents and records. These procedures are detailed here.

7.1. Management of GSI Documents and Records

The GSI PI is responsible for delegating authority for the development of GSI documents and records, as well as providing a timeframe in which to start and complete the document. In general, it is this person—the "Document Manager"—who is also responsible for the document's management. The Document Manager works in conjunction with the GSI PI to determine document format, scope, audience, length, etc. The Document Manager also works with GSI quality management officers to coordinate assignment of a specific and unique GSI document code.

Once complete, the Document Manager is responsible for distributing the document to the GSI PI, and other GSI senior research personnel (if required) for review. She/he is also responsible for maintaining a master version of the document on file, and also on GSI SharePoint. Once complete, the final version of the document is also saved in the appropriate subfolder on GSI SharePoint.

7.2. Format

At a minimum, all GSI documents and records must include the following specifications. The unique document code must be placed in the top right hand corner of the document header as well as the date and number of pages. Codes are provided by the GSI Senior Quality Systems Officer. The document cover page must include the GSI logo as well as the title and authors.

7.3. Revision

Changes to documents must be recorded on a record of amendments sheet that is attached to the original document. The record must describe the revision as well as the date. GSI quality management personnel are responsible for updating the record of amendments for all quality documents (i.e., QMP, QAPPs, SOPs, etc).

7.4. Documents and Records Maintenance

GSI quality management personnel are responsible for maintaining on file and on GSI SharePoint a matrix of all GSI documents and records. The matrix includes the following headings: document type (i.e., SOP, QAQC, findings report, form, etc), document code, title, manager, status and date.

GSI quality management personnel are also responsible for maintaining all documents and records for a period of five years unless custody is transferred using a chain of custody form. Electronic versions of GSI documents and records are saved to the GSI SharePoint website (www.greatshipsinitiative.info). Hard copies of GSI documents and records are scanned and also saved to the GSI SharePoint website. Due care and diligence is taken to properly dispose of documents and records that are no longer required after the five year period has lapsed. Disposal procedures involve electronic deletion of documents and records from the GSI SharePoint website and the personal computers of GSI personnel, as well as manual shredding of hard copies.

8. COMPUTER HARDWARE AND SOFTWARE

8.1. Hardware and Software

In general, it is the responsibility of the individual organization of which GSI personnel are employees to maintain computer hardware and software. For example, NEMWI is responsible for maintaining up-to-date computers and software for the GSI PI and the GSI Senior Quality Systems Officer. LSRI and NRRI are responsible for maintaining up-to-date computers and software for GSI personnel who are employees of these organizations. In cases where the purchase of computer hardware and software is driven by GSI project requirements, these systems and programs are purchased with GSI operating funds.

8.2. Policy and Appropriate Use

Due to the unique nature of GSI in that it is “virtual” organization, GSI personnel must comply with the technology policies and appropriate use requirements of the specific organizations to which they are employed. For example, LSRI staff must adhere to the University of Wisconsin-Superior’s Appropriate Use Guidelines and Information Assurance Policy.

8.3. Data Security

GSI data is secured through the use of the servers and domains of the individual organizations to which GSI personnel are employees. For example, NEMWI employees achieve domain security through the use of NEMWI-specific Windows Network log-in accounts which are password protected. Data is saved onto the NEMWI secure server which also requires a log-on and password to access remotely. LSRI employees use the UWS domain and LSRI server to store

GSI data. Domains and servers require eligible username and passwords for access. The servers are also backed up on a regular basis to avoid loss of data following hardware failure.

8.4. Data Sharing and Backup

GSI uses the Microsoft SharePoint program to securely share data. The program is accessed via the website www.greatshipsinitiative.info which is hosted by the company 1&1. Each SharePoint user has a unique log-in and password and access is not granted to the site without these specifics. GSI SharePoint is used as an intranet for sharing and storing information among GSI personnel and relevant stakeholders. It provides an online community for document collaboration as well as an alternative storage and back-up location for GSI data. The site consists of a homepage from where users can access specific subfolders including administration, biological test activities, QAQC, financial and budget documents, outreach, etc. The site is maintained by the GSI Senior Quality Systems Officer with user access restricted only to the subfolders relevant to their specific role within GSI.

9. PLANNING

In order to accomplish its mission and objectives, GSI must effectively undertake independent status-testing services for developers of ballast treatment systems. These activities can only be successful with systematic planning, with the level of effort commensurate with the importance and intended use of the work, available resources and specific needs of the project. GSI uses a three tiered system to plan its research activities, outlined below.

9.1. GSI Advisory Committee Approval

At least three times a year, the GSI PI meets with the GSI Advisory Committee and the GSI Financial Manager to discuss GSI's upcoming research activities. Existing grant requirements and current and potential GSI awards for services to developers of ballast treatment systems are taken into account during the process, as are available and potential funding sources. The Advisory Committee approves the research agenda, and GSI implements research commensurate with the agenda.

9.2. GSI Senior Personnel

Following approval from the GSI Advisory Committee, the GSI PI convenes senior GSI research personnel to discuss proposed plans of work. During this series of meetings and communications, the following ten steps are discussed with regards to project planning:

- Step 1 – Problem identification.
- Step 2 – Project purpose, goals and objectives.
- Step 3 – Project timeframe and schedule.
- Step 4 – Project design and implementation.

- Step 5 – Resource requirements including funding, infrastructure and equipment.
- Step 6 – Roles and responsibilities of personnel.
- Step 7 – Data collection, analysis, handling and custody.
- Step 8 – Performance measures.
- Step 9 – QAQC activities.
- Step 10 – Project products and reporting requirements.

The GSI PI is responsible for documenting all steps of the planning process. Draft documents are distributed to GSI senior research personnel for further discussion; finalized documents are distributed to all relevant personnel as well as saved to the GSI SharePoint intranet site.

9.3. GSI Quality Management Personnel

Once project specifics have been identified, GSI quality management officers liaise with the GSI PI, and relevant senior research personnel to discuss planned project performance measures and QAQC activities in more detail. This includes a discussion of data quality objectives and performance criteria, data generation and analysis, and other QAQC metrics. If existing quality system activities will not meet the demands of the planned project, GSI quality management officers will designate responsibility and a timeline for updating quality system documents including QAPPs and SOPs.

10. IMPLEMENTATION OF WORK PROCESSES

GSI implements it work processes in accordance with the policies, procedures and guidelines detailed throughout this document. Numerous tools are employed to ensure that GSI projects meet or exceed GSI quality expectations.

10.1. Documentation

As described in section 9, GSI projects require detailed and comprehensive planning. GSI ensures that project activities are carried out according to plan by providing all relevant personnel with copies of planning and technical documents. The GSI PI and GSI Senior Quality Systems Officer are jointly responsible for distributing these documents to relevant personnel, as well as saving copies to the GSI SharePoint website. The GSI PI is also responsible for ensuring that all involved personnel understand the project, its purpose and schedule, its individual components/tasks, and their specific roles and responsibilities.

During implementation of project tasks and activities, the GSI PI can authorize changes or amendments to quality documents where there is need for an immediate revision. Revisions are to be communicated by GSI project-specific QAQC officers. The GSI Senior Quality System Officer is also notified, with the appropriate actions taken to ensure that obsolete or superseded procedures are identified and removed from use. The GSI Senior Quality Systems Officer maintains current version of the revised document on file and also save it to GSI SharePoint.

10.2. Monitoring

The implementation of project work processes, their effectiveness and performance are monitored by the GSI PI and GSI senior research personnel as detailed in section 3.5 of this document. The level of project oversight applied is commensurate with the importance of the particular project and the intended use of the project's results. The GSI PI is wholly responsible for issuing stop/go orders on day-to-day test activities, as well as stop/go orders on any SOP deviations deemed necessary during testing.

10.3. Communication

Due to the virtual nature of GSI, communication is critical to the success of GSI projects and activities. As such GSI uses a combination of conference calls, emails, telephone calls and face to face meetings to communicate project planning and implementation activities between personnel. The small nature of GSI makes informal communication the easiest and most effective method of communication.

GSI also uses the capabilities of its SharePoint intranet website to store and share documents. Another important feature of SharePoint is the calendar function which the GSI PI uses to schedule activities and events, and all GSI personnel use to mark vacations and other times they are not available.

10.4. Dispute Resolution

Implementation of quality management activities may sometimes result in disagreements among involved parties. When these disputes occur, resolution is sought at the lowest management level possible. GSI personnel attempt to resolve the dispute through discussion and negotiation. Final resolution is made by the GSI PI when negotiations do not resolve the issue.

11. ASSESSMENT AND RESPONSE

GSI quality management personnel utilize various tools to assess the GSI quality system. Based on these activities, GSI quality personnel produce several types of reports including project-specific QAQC reports and an annual GSI quality system report.

11.1. Assessment

GSI assesses its quality system on a project by project (or test by test) basis using a variety of tools. In this situation, one project/test is defined as a series of trials of a specific ballast treatment system, i.e., one test may constitute a set of five trials of a ballast treatment system at the GSI land-based facility. The purpose, procedural details, and implementation frequency of each of these assessment tools are outlined below.

11.1.1. Project-Specific QAPP Audits

GSI QAQC Officers assess the implementation of project-specific QAPPs during each test of a ballast treatment system. At the end of the test duration, the officers provide a report to the GSI Senior Quality Systems Officer and GSI PI. The report includes a table listing deviations to the specific QAPP associated with the testing. The following table headings are to be used:

- QAPP Section
- QAPP Page No.
- Description
- Deviation/Inconsistency
- Date
- GSI Personnel
- Reconciliation/Corrective Act

The report also includes an assessment of personnel training requirements and certification, as well as procedures for storing and archiving documents and records; sample labeling, handling and custody requirements; and instrument and equipment maintenance. GSI QAQC Officers post final copies of the QAPP audit reports to the GSI SharePoint website for archiving and storage.

11.1.2. Project-Specific SOP Audits

GSI QAQC Officers assess the implementation of project-specific SOPs during each test of a ballast treatment system. At the end of the test duration, the officers provide a report to the GSI Senior Quality Systems Officer and GSI PI. The report includes a table listing deviations to the specific SOPs that were used during the testing. The following table headings are to be used:

- SOP Code
- SOP Title
- Description
- Deviation/Inconsistency
- Date
- GSI Personnel
- Reconciliation/Corrective Act

GSI QAQC Officers post final copies of the SOP audit reports to the GSI SharePoint website for archiving and storage.

11.1.3. Project-Specific Data Recording and Archiving Audits

Following completion of test activities associated with a specific ballast treatment test, GSI QAQC Officers verify data recording and archiving procedures by randomly evaluating data recording forms and field notebooks for completion, compliance and correct storage procedures.

This includes the GSI Land-Based RDTE Facility Daily Safety Check List, zooplankton enumeration datasheets, phytoplankton enumeration datasheets, sampling station logs, chain of custody forms, etc. GSI QAQC Officers also undertake regular random data verification checks by comparing electronic records (i.e., in database or Excel format) with raw datasheets (i.e., paper forms). This is a manual inspection process and though rather time consuming, is an essential procedure for discovering errors. Findings are summarized in a report provided to the GSI Senior Quality Systems Officer and GSI PI. Final reports are saved to GSI SharePoint for storage and archiving.

11.1.4. Project-Specific Data Quality Assessments

Following completion and verification of a data set associated with a specific ballast treatment test, GSI QAQC Officers determine if the data quality objectives outlined in the relevant GSI QAPP have been successfully met. Findings are summarized in a series of tables detailing the data quality indicators by type of analysis, e.g., zooplankton, phytoplankton, microbes, etc. Reports are provided to the GSI Senior Quality Systems Officer and GSI PI; final copies are stored on GSI SharePoint.

11.1.5. Project-Specific Performance Criteria Assessments

Following completion and verification of a data set associated with a specific ballast treatment test, GSI QAQC Officers also determine if the performance criteria outlined in the relevant GSI QAPP have been successfully met. Findings are summarized in a table detailing the performance criteria and test results. The table is provided in a report to the GSI Senior Quality Systems Officer and GSI PI. Final copies of the report are saved to GSI SharePoint for storage and archiving.

11.2. Response

11.2.1. Corrective Action Reports

GSI quality management personnel convene to discuss quality system audits and assessment outcomes following completion of a specific ballast treatment test. Personnel use the results of audits and assessments to develop recommendations and directives for actions to correct work or data that do not conform to GSI quality standards. They then compile a report listing the recommendations and directives. This report is provided to the GSI PI, relevant GSI senior research team personnel and to those individuals involved in the follow-up to ensure visibility and timeliness. Reports are also posted to the GSI SharePoint website for storage and archiving.

11.2.2. Quality System Annual Report

The GSI Senior Quality Systems Officer is responsible for writing an annual report of GSI quality system activities. The report is to be completed in the first quarter of each year for the previous calendar year’s activities. The report includes:

- A summary of the year's projects and activities;
- A summary of the year's project-specific audits, assessments and responses;
- A list of quality system documentation and SOPs developed during the last year;
- A list of quality management training GSI personnel received during the last year;
- A discussion on the status of the GSI quality system including strengths, weaknesses, successes and problems, and recommendations for improvements; and
- An assessment of the adequacy of the GSI QMP and recommended changes.

Once drafted, the GSI Senior Quality Systems Officer sends the report to the GSI Senior QAQC Officer for review and comment. A finalized version is then sent to the GSI PI. Finalized reports are also posted to the GSI SharePoint website for storage and archiving, and distributed to relevant GSI research team members.

12. QUALITY IMPROVEMENT

Quality improvement is one of the four operating principles that guide the GSI's quality management system. The system is designed and implemented to facilitate the identification and communication of areas requiring improvement. For example, open lines of communication between the GSI PI, quality management officers, and GSI senior personnel and technicians; regular quality system training; and recurring data quality audits, assessments and reports all provide opportunities to identify and communicate areas for improvement.

In addition, GSI undertakes periodic reviews of its quality system program, as well as its specific project areas, i.e., through review and revisions of QAPPs and SOPs. Combined, these activities provide the necessary feedback to improve the GSI's quality system. This feedback can then also be incorporated into a revised QMP. GSI quality management personnel also annually review the QMP to determine if the document is still relevant and/or reflective of current GSI quality system policies and procedures, and if not make the necessary improvements to the document.